



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 725

[EPA-HQ-OPPT-2010-0994; FRL-9350-6]

RIN 2070-AD43

Trichoderma reesei; Proposed Significant New Use Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under the Toxic Substances Control Act (TSCA) for the genetically modified microorganism identified generically as *Trichoderma reesei* (*T. reesei*). This microorganism was the subject of a Microbial Commercial Activity Notice (MCAN). EPA believes this action is necessary because the use of this genetically modified *T. reesei* under certain conditions may be hazardous to human health and the environment. This proposed rule would also establish a mechanism to allow EPA to evaluate an intended use and its conditions, and to prohibit or limit that activity before it occurs, if EPA determines it may be hazardous.

DATES: Comments must be received on or before *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2010-0994, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2010-0994. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2010-0994. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use products that contain living microorganisms subject to TSCA, especially if you know that your products contain or may contain *T. reesei*. Potentially affected entities may include, but are not limited to:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the list of chemical substances excluded by TSCA section 3(2)(B) and the applicability provisions in § 725.105(c) for SNUR related obligations. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under

FOR FURTHER INFORMATION CONTACT.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemical substances subject to these SNURs must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 725.920), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing this SNUR for the genetically modified microorganism identified generically as *T. reesei* (MCAN J-10-2). This proposed rule would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the microorganism for any activity designated as a significant new use.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” (see 40 CFR part 725, subparts L and M). EPA must make this determination by rule after considering all relevant factors, including the TSCA section 5(a)(2) factors, listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 725.105(c).

EPA has interpreted the TSCA section 3(2) definition of “chemical substance” as authorizing EPA to regulate microorganisms under TSCA. See the **Federal Register** issue of April 11, 1997 (62 FR 17910) (FRL-5577-2).

C. Applicability of General Provisions

General provisions for SNURs for microorganisms appear in 40 CFR part 725, subpart L. These provisions describe persons subject to the proposed rule, recordkeeping requirements, exemptions to reporting requirements, and applicability to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700. Persons subject to this SNUR must comply with the notice requirements under TSCA section 5(a)(1)(A) and must submit a MCAN, using the procedures set out in 40 CFR part 725, subpart D, and additional “Significant New Uses of Microorganisms” procedures at 40 CFR part 725, subpart L.

Under 40 CFR part 725, EPA has adopted a more narrow interpretation of the TSCA section 5(h)(3) exemption for small quantities used in research than it has for other chemical substances under 40 CFR part 721. Under § 725.3, EPA has defined small

quantities solely for research and development as “quantities of a microorganism manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that meet the requirements of § 725.234.” Any other research and development activity of a microorganism subject to a SNUR must comply with the TSCA section 5(a)(1)(A) notification requirements unless that activity has been excluded from coverage under the SNUR. See § 725.3, subparts E and F of 40 CFR part 725, and the April 11, 1997 **Federal Register** document. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors specifically enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the chemical substance that is the subject of this proposed SNUR, EPA considered the available information relating to the four bulleted factors listed in TSCA section 5(a)(2) factors listed in this unit, and other relevant factors. This includes relevant information about the toxicity of the chemical substance and likely human exposures and environmental releases associated with possible uses. See the risk assessment in the docket under docket ID number EPA-HQ-OPPT-2010-0994 for this information and other relevant factors.

IV. Substance Subject to this Proposed Rule

EPA is proposing to establish significant new use and recordkeeping requirements for only the microorganism identified generically as *T. reesei*, genetically modified as described in MCAN J-10-2. This will be codified in 40 CFR part 725, subpart M. Any *T. reesei* microorganism with genetic modifications other than those described in MCAN J-10-2 would not be subject to this SNUR and will require submission and EPA review of a separate MCAN.

MCAN Number J-10-2

Chemical name: *Trichoderma reesei* (MCAN J-10-2) (generic).

Chemical Abstracts Service (CAS) Registry Number: Not available.

Use: The MCAN states that the generic (non-confidential) use of the microorganism will be to produce enzymes for ethanol production.

Basis for action: When used to produce enzymes that can release sugars from de-lignified plant materials, human and environmental exposures to live *T. reesei* cells are low, due to

the containment and inactivation procedures specified in the MCAN. These containment and inactivation procedures are consistent with standard industry practices and those delineated in 40 CFR 725.422(d). These procedures include the use of equipment to minimize aerosol releases from the facility, and the use of inactivation methods that reduce the number of viable cells by at least 6 logs (i.e., 10^6) in the liquid and solid waste streams. More importantly, the manufacturing process described in the MCAN relies on the typical submerged standard industrial fermentation process for enzyme production, wherein the microorganism is grown in liquid broth culture in the absence of solid materials or solid surfaces, the fermentation is terminated prior to the microorganism entering the stationary phase of growth, and the enzyme is separated from the microbial biomass which is inactivated prior to disposal. Therefore, EPA determined that the proposed manufacturing, processing, or use of the microorganism as described in the MCAN is not expected to present an unreasonable risk. However, EPA has determined that use of the microorganism under other conditions may result in adverse human health and environmental effects. Specifically, where growth on solid plant material or insoluble substrate occurs, *T. reesei* has been shown to produce a secondary metabolite known as paracelsin, which is a peptaibol. Peptaibols are small linear peptides of 1,000-2,000 Daltons characterized by a high content of the non-proteinogenic amino acid alpha-amino-isobutyric acid (Aib), with a *N*-terminus that is typically acetylated, and a *C*-terminus that is linked to an amino alcohol, which is usually phenylalaninol, or sometimes valinol, leucinol, isoleucinol, or tryptophanol. Peptaibols are associated with a wide variety of biological activities and have antifungal, antibacterial, sometimes antiviral, antiparasitic, and neurotoxic activity. Paracelsin has been shown to have

toxicity toward mammalian cells such as hemolytic activity on human erythrocytes and cytotoxicity to rat adrenal medulla PC12 (pheochromocytoma) cells. Paracelsin has also been shown to exhibit cytotoxicity to Gram-positive bacteria, to human erythrocytes, and to other mammals such as aquatic indicator species. Additional information relating to the assessment of this chemical substance and paracelsin, including a sanitized EPA risk assessment and a list of references used, is available in the docket under docket ID number EPA-HQ-OPPT-2010-0994.

Recommended testing: EPA has determined that the results of the following studies would help characterize any potential human health and environmental effects of the MCAN substance:

1. Investigation of whether paracelsin will be produced, and at what levels if the genetically modified *T. reesei* is grown on various plant biomass materials for different durations under various fermentation conditions in cellulosic biomass facilities.
2. If paracelsin is produced, a study of whether paracelsin would be denatured/inactivated during production and processing.
3. If paracelsin is released from the facility, a study of whether paracelsin would be degraded/inactivated during wastewater treatment.
4. If released to the environment, studies on the persistence, stability, dissemination, accumulation, and the potential resulting biological activity of paracelsin with exposure to aquatic and terrestrial organisms in the environment.
5. Studies to determine the ability of the MCAN microorganism to survive in the environment relative to the survival of the unmodified parent or recipient strain, and to

assess its competitiveness with other fungi in the environment. This study may require some supplementation with one or more carbon sources and the use of various soil types.

6. A study to determine survival of the fungus during an anaerobic fermentation for production of ethanol by an ethanologen, and survival of the fungus during ethanol distillation or at the distillation temperature for ethanol.

CFR citation: 40 CFR 725.1077.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the specific *T. reesei*, modified as described in MCAN J-10-2, EPA determined that certain fermentation conditions, other than the typical submerged standard industrial fermentation process for enzyme production described in Unit IV., could result in increased exposures thereby constituting a “significant new use.”

Specifically, EPA is concerned that where growth on solid plant material or insoluble substrate occurs, *T. reesei* has been shown to produce a secondary metabolite known as paracelsin, which is associated with a variety of toxic effects to mammalian and bacterial cells. Use of the MCAN microorganism without the specific containment or inactivation controls listed in the MCAN, described in Unit IV., may result in adverse human health and environmental effects. Based on the descriptions of manufacturing, processing, and use in the MCAN J-10-2, the Agency believes that uses of the organism covered by the proposed definition of a significant new use are not currently ongoing.

B. Objectives

EPA is proposing this SNUR for a chemical substance that has undergone review to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to determine whether regulation of prospective manufacturers, importers, or processors of a listed chemical substance is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7, and impose any necessary requirements before the described significant new use of that chemical substance occurs.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available electronically at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant “new” use, EPA must determine that the use is not ongoing. EPA solicits comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** issue of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the proposed rule became final, and then argue that the use was ongoing before the effective date of the final rule. Thus, any persons who begin commercial manufacture, import, or processing activities with the microorganism that would be regulated through this proposed rule will have to cease any such activity before the effective date of the final rule, if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA has promulgated provisions to allow persons to comply with this proposed SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 725.912(a), the person would be considered exempt from the requirements of the SNUR.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 725.25(a)(2)). However, upon review of MCANs and SNUNs, the Agency has the authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

The recommended testing specified in Unit IV. may not be the only means of addressing the potential risks for the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will respond by taking action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior submission. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substance.
- Potential benefits of the chemical substance.
- Information on risks posed by the chemical substance compared to risks posed by potential substitutes.

VIII. SNUN Submissions

Persons subject to this SNUR must comply with the notice requirements under TSCA section 5(a)(1)(A) and must submit a MCAN, using the procedures set out in 40 CFR part 725, subpart D, and additional “Significant New Uses of Microorganisms” procedures at 40 CFR part 725, subpart L. SNUNs must be submitted to EPA on EPA Form No. 6300-07, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 725.25 and 40 CFR 725.27. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substance subject to this proposed rule. EPA’s complete Economic Analysis is available in the docket under docket ID number EPA–HQ–OPPT–2010–0994.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish a SNUR for a chemical substance that was the subject of a MCAN. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act

According to the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been

approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this proposed rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR would not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUN submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit IX. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted

by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 725

Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

Dated: June 1, 2012.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 725--[AMENDED]

1. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

2. Add § 725.1077 to subpart M to read as follows:

§ 725.1077 *Trichoderma reesei* (generic).

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically modified microorganism identified generically as *Trichoderma reesei* (MCAN J-10-2) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2)(i) The significant new use is any manufacturing, processing, or use of the microorganism other than in a fermentation system that meets all of the following conditions:

(A) Submerged fermentation (i.e., growth of the microorganism occurs beneath the surface of the liquid growth medium).

(B) No solid plant material or insoluble substrate is included with the microorganism for fermentation.

(C) Any fermentation of solid plant material or insoluble substrate, to which fermentation broth is added, is initiated only after the inactivation of the microorganism as delineated in 40 CFR 725.422(d).

(ii) [Reserved]

(b) [Reserved]

[FR Doc. 2012-14242 Filed 06/12/2012 at 8:45 am; Publication Date: 06/13/2012]